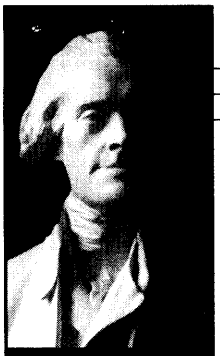

Jeffersonian Principles in Action

ALEC Testimony

Testimony Delivered to the HHS Task Force on Drug Importation

Rockville, Maryland
May 5, 2004

By James Frogue
Director of the Health and Human Services Task Force
American Legislative Exchange Council

Good morning. My name is James Frogue and I am director of the Health and Human Services Task Force at the American Legislative Exchange Council (ALEC). ALEC is a 30-year-old organization made up of 2,400 state legislators from all 50 states. We are the largest bipartisan organization of individual state legislators in the country. Our membership also includes approximately 300 private sector members. We receive no taxpayer dollars. As task force director, it is my job to work with our legislator and private sector members to develop policies that maximize patient empowerment.

ALEC is divided up into ten different task forces. Other task forces address issues such as education, tax and fiscal policy, the environment, and technology to name a few. Each task force can have a maximum of three legislators per state. ALEC task forces meet three times each year to discuss the issues of greatest importance to our legislator members. At each meeting, task force members consider model legislation that, if passed, goes on to become available to all ALEC members to use as they see fit in their respective states.

We just returned from Austin, Texas where last weekend we completed our annual Spring Task Force Summit. The HHS Task Force passed the attached resolution by a vote of 52-0. The purpose of the resolution was to recognize the dangers inherent in importation, acknowledge the good work but limited scope of the FDA, and place ALEC clearly on record as opposed to the illegal importation of non-FDA approved prescription drugs due to concerns about safety. An announcement from the FDA on September 29 of last year found that nearly 90 percent (1,019 out of 1,153) of mail parcels arriving from foreign countries that had prescription drugs, contained medications that violated American drug safety laws. For some elements of this debate to minimize concerns over safety is simply irresponsible in light of this single study.

Beyond the very legitimate risks associated with importation is the question of whether it would actually be effective in lowering drug prices for American consumers. In order for importation from Canada, for example, to place significant downward pressure on American retail prices there would have to be a tidal wave of product coming from north of the border. That simply cannot and will not happen. Canada represents approximately 2 percent of the global prescription drug market with the U.S. around 50 percent. Under no circumstances would a market as small as Canada's set the broad prices for a market 25 times its size. This is due to the simple fact that drug manufacturers can control the number of their pills on the market and they will not indefinitely sell Manitoba wholesalers exponentially more product than is needed for citizens of Manitoba.

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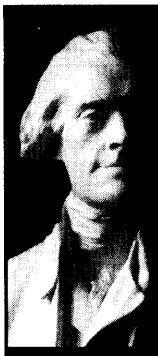

Jeffersonian Principles in Action

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The rights of patent holders are clearly enshrined in both American law and international trade agreements. Title 35 U.S.C. Section 271 state that, "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States and patented invention during the term of the patent infringes that patent." Article 1709 of NAFTA and Articles 27 and 28 of the World Trade Organization's Trade Related Intellectual Property Agreement also secure the rights of patent holders. This being the case, manufacturers of patented medications have domestic and international legal recourse against middlemen who seek to violate the terms of private licensing agreements. To suggest, as some have both here and abroad, that drug makers should be sanctioned, forced to sell their product on unfavorable terms, or be subject to compulsory licensing is a full frontal assault on intellectual property rights, the kind that would be unthinkable if the subject were movies or software.

Just last week, the Congressional Budget Office released a six page paper entitled "Would Prescription Drug Importation Reduce U.S. Drug Spending?" Their analysis concluded that H.R. 2427 introduced by Representatives Gil Gutkneckt (R-MN) and Rahm Emanuel (D-IL), that would permit importation from a broad range of industrialized countries, would lower ten year drug spending by 1 percent. They attributed this negligible savings largely to the ability of patent holders to control the amount of their product on the market. It is up to policymakers to decide if a 1 percent savings is worth the very significant risk.

As a result of reduced supplies in Canada, Canadian pharmacies and therefore patients are beginning to experience drug shortages. Health Canada Assistant Deputy Minister Diane Gorman stated that she, "regards this as a very serious matter." Michele Fontaine, vice president of the Coalition for Manitoba Pharmacy recently experienced a shortage of drugs to treat cancer and high blood pressure. Suffice it to say, Canadian politicians are not going to sit idly by while medications needed by their constituents are being sent to America. Chalk up this impediment as another major reason why American consumers are highly unlikely to see widespread Canadian prices in this country.

Let us keep in mind exactly who are the bulk of Americans traveling out of the country or going on-line to get foreign drugs. They are mostly low-income, uninsured, and eligible for Medicare. They are not Members of Congress or the 9 million federal employees, their dependants, and retirees who get to choose from a wide array of competing, comprehensive, private insurance plans all of which have excellent drug coverage. Indeed, it was the Federal Employees Health Benefits Plan that should have been the model for Medicare reform last year. It has been around longer than Medicare and has provided more comprehensive services to its beneficiaries.

Thank you for your attention and I look forward to any questions.

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Resolution Concerning the Prohibition of Imported Prescription Drugs

WHEREAS, the use of safe and legal prescription drugs improves the quality of care and helps patients live healthier, longer, and more productive lives while keeping them out of more costly acute care settings in the long term, and

WHEREAS, the Food, Drug, and Cosmetic Act (FDCA) governs the manufacture, sale, and distribution of drugs in interstate commerce, and under the FDCA, every new drug must be approved by the Food and Drug Administration (FDA) prior to marketing, and also under the FDCA, approvals are specific to each product, and all prescription drugs must be accurately labeled and may not be dispensed without an order from a licensed practitioner, and

WHEREAS, virtually all prescription drugs imported into the United States, other than those imported by the original manufacturer, pose serious safety concerns and violate these provisions of the federal law; such as those recently uncovered by a U.S. Customs and FDA investigation, which found that 88% (1,019 of 1,153) contained unapproved drugs, such as mislabeled, misbranded, expired, and mishandled drugs that might cause patient health problems, and

WHEREAS, the importation of drugs from foreign countries opens the currently secured distribution system established by the FDCA, thereby increasing the likelihood that counterfeit drugs, dangerous narcotics and deliberately contaminated material would endanger the health of U.S. citizens, and

WHEREAS, national pharmacy groups with a focus on patient health and safety have stated that the safety of imported drugs cannot be guaranteed and may result in patient harm, and

WHEREAS, the FDA's Personal Importation policy, which merely states as a matter of FDA enforcement discretion, an individual may import small quantities of drugs which are intended for serious conditions and which are not available domestically, does not alter the requirements of the federal law, and

WHEREAS, consumers victimized by imported drugs have included the most vulnerable patients including seniors, children, and the underserved.

NOW, THEREFORE, BE IT RESOLVED that the American Legislative Exchange Council supports the FDA's efforts to ensure the safety and quality of prescription drugs and opposes the illegal importation of non-FDA approved prescription drugs because of safety concerns.

Passed by the HHS Task Force by a vote of 52-0 on Saturday, May 1, 2004 at the Spring Task Force Summit in Austin, Texas.